PREPARING STATEMENTS OF WORK FOR PROCURING ANALYTICAL CHEMISTRY

Purpose

This Meteorology and Air Quality Group (MAQ) procedure describes how to write and implement a statement of work for analytical chemistry and how to assess the overall adequacy of analytical contractor laboratories in support of the air sampling projects with the group.

Scope

This procedure applies to all statements of work prepared for analysis of air filters, silica gel distillate, or other media used in sampling the air for compliance or environmental monitoring.

In this procedure

Signatures

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General information about this procedure

Attachments

This procedure has no attachments.

History of revision

This table lists the revision history and effective dates of this procedure.

Revision	Date	Description Of Changes
0	2/6/98	New document.
1	7/2/02	Quick-change revision to delete obsolete attachments.

Who requires training to this procedure?

The following personnel require training before implementing this procedure:

- analytical chemistry coordinator
- project leaders who need chemical analyses for their projects

Training method

The training method for this procedure is “self-study” (reading) and is documented in accordance with the procedure for training (MAQ-024).

General information, continued

Definitions specific to this procedure

Defensible Data Package: A data package which the MAQ analytical chemistry coordinator and QA officer believe sufficient (based on EPA Contract Laboratory Program and best professional judgment) to prove the validity of chemistry results.

Electronic Data Deliverable (EDD): The computer-compatible file that is delivered to MAQ from the analytical laboratory in the SOW-specified format via Internet, e-mail, or diskette from which analytical chemistry data may be uploaded directly into databases.

Statement of Work (SOW): A statement of work is a list of specifications and requirements which analytical laboratories must meet, in order to do work for MAQ.

References

The following documents are referenced in this procedure:

- MAQ-024, "Personnel Training"
- MAQ-033, "Analytical Chemistry Data Review"
- MAQ-SOW-01, "General Requirements for all Statements of Work For Analytical Chemistry Support for MAQ"
- MAQ-SOW-06, "Statement of Work for Gross Alpha & Beta Determination in Ambient Air Particulate Filter Samples"

Note

Actions specified within this procedure, unless preceded with "should" or "may," are to be considered mandatory guidance (i.e., "shall").

Preparing statements of work

Why SOWs are used

Statements of work (SOWs) describe and formally transmit MAQ analytical requirements to the laboratory. This allows discussion of specifications and avoids misunderstandings of the necessary quality, documentation, and schedule. It allows exact price estimates to be prepared by the laboratory. The MAQ analytical chemistry coordinator contracts with analytical laboratories, using Statements of Work to describe the specifications, such as laboratory practices, quality control needs, and the documentation which the laboratory is required to transmit to MAQ with the analytical results. These document specifications are based on EPA guidance, the EPA Contract Laboratory Program (CLP), industry standards from the commercial analytical laboratory sector, and on the best professional judgment of the analytical chemist regarding the documentation that will be needed to demonstrate the quality of the data to interested parties.

SOWs are issued as controlled documents under the group's document control system.

Why data packages are needed

Responsibility for accurate reporting of air quality data rests with MAQ. Since analytical chemistry is a component of the data, MAQ must be prepared to demonstrate to concerned parties that the chemistry data are accurate and of known quality. The analytical chemistry is done by laboratories outside the group. MAQ requires not only that analytical results are reported, but also that supporting information, which is expected to be sufficient to demonstrate the accuracy and data quality at a later time, accompany the results.

Preparing statements of work, continued

Current package content requirements

Current MAQ SOWs specify that the data package returned by the laboratory contain the following information (in no specified order) in a sequentially numbered report:

- A narrative letter providing an overview of normal operation, status of control, and describing in detail any departures from normal operation.
- Signed and dated MAQ sample chain of custody and lab custody forms.
- Positive sample identification in all reports
- Signatures or initials and dates at each work and review stage.
- Copies of bench sheets (which follow notebook rules), documenting samples, standards and QC preparations, with weights and volumes
- Sample data summary containing MAQ sample ID, Lab sample ID, results, uncertainty, MDA, units, and dates.
- QC data summary for blanks, spikes, duplicates, laboratory control samples, etc. This summary is expected to contain the Lab-ID, results, uncertainty, MDA, units, dates, expected values, and control limits.
- Traceability documentation (e.g. prep logs and certificates) for tracers, spikes, and QCs.
- Spectra and spectral processing data, such as the following:
  1. For radiochemistry/alpha spectroscopy, tracer recoveries and spectra with regions of interest clearly marked;
  2. For gamma spectrometry, spectra and accompanying tables of isotopes, containing channels and energy data for required standard library peaks and for unidentified peaks;
  3. For tritium determination, quench curves and/or tSIE tables;
  4. For gross alpha/beta, curves, factors, and/or equations for cross-talk, mass correction and efficiencies.
- For each sample, blank, and QC, in sufficient detail to allow MAQ to reconstruct manual calculations or those done by manufacturer or in-house computer calculations, the following data where appropriate:
  - instrument manufacturer
  - Detector ID
  - Efficiency
  - Resolution
  - Sample ID
  - Sample count or rate
  - background count or rate
  - Spectra
  - Spectral ROI
  - software manufacturer
  - software subroutine ID
  - equations used
  - sample calculations
  - Such needed factors as:
    - tracer recovery
    - sample mass used
    - cross-talk

Preparing statements of work, continued

Structure of the SOWs

Generally, the SOWs are created in two parts: the "general" requirements (see see SOW-01) that are part of all SOWs, and the analyte-specific part or parts that describes the analyses requested (see SOW-06 for an example).

Steps to prepare an SOW

To prepare a statement of work for analyses, follow the steps below.

Step	Action
1	Consult the appropriate federal or state regulation, MAQ QA project plan, and/or project leader to determine analytical requirements such as analyte, MDA, methodology allowed, and schedule.
2	Using EPA CLP SOWs, other guidance, and best professional judgment, decide on the information and documentation to be required in the data package. See SOW-01 for the minimum requirements of all SOWs.
3	Prepare the SOW, using older SOWs as guides, modifying where necessary to reflect current needs and budgets (see SOW-06 for an example). Ensure package content requirements listed on previous page are clearly specified in the SOW.
4	Obtain peer review of SOW draft from project leaders, project staff, and quality assurance officer.
5	Finalize SOW considering all comments from step 4.
6	Prepare appropriate checklists from the SOW content, according to the appropriate chapter of MAQ-033. Incorporate these checklists as attachments to the SOW. **NOTE**: These checklists may be modified after the first deliverables are received and as the required content changes with time.

Purchasing analytical chemistry with SOWs

How SOWs are used

SOWs are used 1) to solicit bids from the potential supplier, and 2) as part of the contract with the supplier to specify the deliverables (analytical chemistry data and supporting information) being purchased. As part of the purchasing system, BUS rules must be followed. Allow up to a year to get the entire procurement process accomplished and begin sample shipment.

SOW with an internal lab

When dealing with internal laboratories, negotiate any terms and conditions of the SOW, prepared as described above, to obtain chemistry data in a timely, cost-effective manner, with required quality and documentation.

SOW with an external lab

When it is necessary to contract with an external laboratory for a new procurement, contact the ESH-BUS representative, and inform him/her of the need to obtain new services and discuss quality specifications. Obtain standard price lists, but do not negotiate prices. In a new procurement mode, where competitive pricing is required, it may prove necessary to reiterate the process of specifying technical needs and obtaining price "estimates." Working through the ESH-BUS representative, adjust MAQ requirements of the SOWs, as needed to obtain affordable chemistry data in a timely manner, with required quality and documentation.

Take the technically complete SOW to the ESH-BUS representative. A LANL procurement that contains the SOW will be generated, and final pricing will be obtained from the lab.

Negotiating with currently contracted labs

When dealing with a currently contracted external laboratory for additional work of the same type, prices may be discussed for minor changes. Keep the ESH-BUS representative informed, since major changes in data quality objectives within any sampling program may require repeating the entire procurement process.

Shipping samples to contracted lab

Ship samples and paperwork as described in the appropriate sampling or composite procedures. When shipping more samples for exactly the same work, samples may be shipped using the same SOW, up to purchase authorities allowed.

Quality assessment of analytical chemistry suppliers

On-site assessments of vendors

SOWs are used in the LANL purchasing process to describe to the supplier the specifications of the product (analytical chemistry data and supporting information) being purchased. Periodic, formal assessment of each supplier should be performed to ensure that each has the capability to meet the general requirements of our SOWs and that each analytical laboratory is operated ethically and according to generally accepted "Good Laboratory Practices." Some of the latter are provided in NIST and EPA guideline documents and some are developed by the industry themselves. These assessments should also provide assurance that our work is actually conducted under each vendor's quality plan and according to their procedures.

Steps to assess supplier

The following steps describe how an assessment process is implemented as part of the overall MAQ quality assurance process:

Step	Action
1	Periodically conduct assessments of continuing suppliers (both internal and external to LANL) and perform a pre-award assessment on any potential new supplier that is being seriously considered for analytical work. Use the requirements in the SOW and the criteria and items listed on the next page to assess and evaluate the supplier's program.
2	Document the observations of all assessments in formal reports and forward the reports to the assessed organization for their factual accuracy review and consideration for corrective action and/or quality improvement.
3	Follow up on any corrective actions proposed by the assessed organizations to ensure timely implementation and to determine its effectiveness.
4	Use the criteria above in combination with professional judgment, knowledge of lab operations, compliance with intent of Clean Air Act provisions, and other information to make a decision on the acceptability of the supplier.

Quality assessment of analytical chemistry suppliers, continued

Performance evaluation assessments of vendors

There are several generally accepted approaches to evaluation of the actual performance of an analytical system/laboratory:

- EPA and NIST good laboratory practice guidance recommends a number of bench-level, laboratory-generated quality control samples: blanks, blank spikes, duplicates, replicates, matrix spikes, matrix spike duplicates, and laboratory control standards (known, calibrated standard run with each batch of samples).
- Several national performance evaluation programs prepare and submit environmental samples on a blind basis to analytical laboratories. These data can be used as a general, overall indicator of the state of control of a laboratory at the time of each Performance Evaluation study. Studies of interest to MAQ are DOE's Environmental Measurement Laboratory's Quality Assessment Program (EML-QAP) and EPA's National Exposure Research Laboratory, Characterization Research Division - Las Vegas (EPA-NERL-CRD-LV) Performance Evaluation Studies (formerly known as the Environmental Monitoring Systems Laboratory - Las Vegas [EMSL-LV] Environmental Radioactivity Cross-Check Program).
- Customers should either prepare or acquire matrix-based, spiked QC samples that are specific to their analytes of interest and the concentration ranges in their samples.

Analytical laboratory QC samples

Evaluate each laboratory's performance in the SOW requirement to provide data on blanks, spikes, replicates, duplicates and Laboratory Control Standards that were run in conjunction with each batch of our samples as part of the final data package. These data are inspected during the validation/verification process (MAQ-033) and databased for tracking, trending and periodic overall evaluation of each laboratory's performance.

National performance evaluation programs

Each supplier is required (by the SOW) to submit copies of the evaluation program's report to MAQ as they become available. These reports are inspected (MAQ-033) and then databased for tracking, trending, and periodic overall evaluation of each laboratory's performance.

MAQ spiked matrix QC samples

Good laboratory practice recommends that at least 5% of the samples submitted to a laboratory be from the customer's QC program. It further recommends that matrix samples be spiked in the range of 3 - 10 times the MDA required, and/or within the normal range of concentrations observed in actual samples.

Records resulting from this procedure

Records

The following records generated as a result of this procedure are to be submitted as records **within 6 weeks of generation** to the records coordinator:

- Completed Statement of Work document (issued as a controlled document under group's document control system)
- reports on assessments of analytical suppliers (when performed)